

04-16-04

Docket 17679 (BOT)



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: CATHERINE TURKEL et al. ) Examiner:  
Serial Number: 10/789,180 )  
Filed: February 26, 2004 ) Art Unit:  
For: METHODS FOR TREATING PAIN )  
AND FOR TREATING A MEDICA- )  
TION OVERUSE DISORDER ) Irvine, California

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Applicant's provide with regard to the patent application entitled METHODS FOR TREATING PAIN AND FOR TREATING A MEDICATION OVERUSE DISORDER, filed herewith one copy of documents of which they are aware, which may be material to the examination of this application, and in respect of which there may be a duty of disclosure under 37 C.F.R. §1.56. A listing of documents submitted is set forth on the attached Information Disclosure Citation (Form PTO-1449).

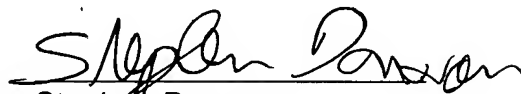
While these documents may be material pursuant to 37 C.F.R. §1.56, their disclosure is not intended to constitute an admission that the documents are prior art in regard to this invention. The filing of this Statement should not be construed to mean that a search has been conducted or that no other material documents or information exists. Please do not hesitate to contact the undersigned should any questions arise regarding this Statement.



The Commissioner is hereby authorized to charge any fees required or necessary for the filing, processing or entering of this paper or any of the enclosed papers, and to refund any overpayment, to deposit account 01-0885.

Respectfully submitted,

Date: April 14, 2004

  
Stephen Donovan  
Registration Number 33,433

Please direct all inquiries and correspondence to:

Stephen Donovan  
Allergan, Inc.  
2525 Dupont Drive, T2-7H  
Irvine, California 92623-9534  
Tel: 714.246.4026  
Fax: 714.246-4249

**CERTIFICATE OF EXPRESS MAIL UNDER 37 C.F.R. § 1.10**

I hereby certify that this Information Disclosure Statement and the documents referred to as enclosed herein are being deposited with the United States Postal Service on this date April 14, 2004, in an envelope as "Express Mail Post Office to Addressee" Mailing Label number EV193717200US addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Susan Bartholomew

Name of person mailing paper

  
Signature of person mailing paper

Date: April 14, 2004



### LIST OF ART CITED BY APPLICANT

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APPLICANT: Catherine Turkel et al.	TITLE: METHODS FOR TREATING PAIN AND FOR TREATING A MEDICATION OVERUSE DISORDER
FILING DATE: February 26, 2004	GROUP:

### U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
	AA	10/194,805		Donovan, Stephen			7/11/2002
	AB	10/423,380		Ackerman, Alan H.			4/25/2003
	AC	10/429,069		Voet, Martin A.			5/2/2003
	AD	10/630,587		Aoki et al.			7/29/2003
	AE	10/731,973		First, Eric R.			12/9/2003
	AF	10/752,869		First, Eric R.			1/6/2004
	AG	60/418,789		Katz, Howard			10/15/2002
	AH	2003 0224019	12/4/2003	Christopher O'Brien			
	AI	5,437,291	8/1/1995	Pasricha et al.			
	AJ	5,670,484	9/23/1997	William J. Binder			
	AK	5,714,468	2/3/1998	William J. Binder			
	AL	5,766,605	6/16/1998	Sanders et al.			
	AM	5,989,545	11/23/1999	Foster et al.			
	AN	6,063,768	5/16/2000	Eric R. First			
	AO	6,139,845	10/31/2000	Stephen Donovan			
	AP	6,299,893	10/9/2001	Schwartz et al.			
	AQ	6,306,423	10/23/2001	Donovan et al.			
	AR	6,312,708	11/6/2001	Stephen Donovan			
	AS	6,358,917	3/19/2002	Carruthers et al.			
	AT	6,423,319	7/23/2002	Brooks et al.			
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	AW	6,464,986	10/15/2002	Aoki et al.			
	AX	6,623,742	9/23/2003	Martin A. Voet			

EXAMINER \_\_\_\_\_ DATE CONSIDERED \_\_\_\_\_

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**FOREIGN PATENT DOCUMENTS**

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION (yes/no)
	BA	DE 101 50 415 A1	5/15/2003	Germany			N
	BK	WO 03/011333	2/13/2003	PCT			Y

**OTHER ART**

(Including Author, Title, Date, Pertinent Pages, etc.)

	CA	Aoki K., et al, <i>Mechanisms of the antinociceptive effect of subcutaneous Botox: Inhibition of peripheral and central nociceptive processing</i> , Cephalalgia 2003 Sep;23(7):649
	CB	Aoki, K., et al., <i>Botulinum toxin type A and other botulinum toxin serotypes: a comparative review of biochemical and pharmacological actions</i> , Eur J. Neurol 2001: (suppl 5); 21-29
	CC	Aoki, K., <i>Physiology and pharmacology of therapeutic botulinum neurotoxins</i> , in Kreyden, O., editor, <i>Hyperhydrosis and botulinum toxin in dermatology</i> , Basel, Karger; 2002; 30: pages 107-116, at 109-110
	CD	Bhattacharya K., et al., <i>Novel uses of botulinum toxin type A: two case reports</i> , Mov Disord 2000; 15(Suppl 2):51-52
	CE	Bigalke H., et al., <i>Botulinum A Neurotoxin Inhibits Non-Cholinergic Synaptic Transmission in Mouse Spinal Cord Neurons in Culture</i> , Brain Research 360;318-324:1985
	CF	Bigalke H., et al., <i>Tetanus Toxin and Botulinum A Toxin Inhibit Release and Uptake of Various Transmitters, as Studied with Particulate Preparations From Rat Brain and Spinal Cord</i> , Naunyn-Schmiedeberg's Arch Pharmacol 316;244-251:1981
	CG	Binz T. et al., <i>The Complete Sequence of Botulinum Neurotoxin Type A and Comparison with Other Clostridial Neurotoxins</i> , J Biological Chemistry 265(16);9153-9158:1990
	CH	Blugerman G., et al., <i>Multiple eccrine hidrocystomas: A new therapeutic option with botulinum toxin</i> , Dermatol Surg 2003 May;29(5):557-9

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	CI	Brem, H., et al, <i>Placebo-Controlled Trial of Safety and Efficacy of Intraoperative Controlled Delivery by Biodegradable Polymers of Chemotherapy for Recurrent Gliomas</i> , Lancet 345;1008-1012:1995
	CJ	Brin, M., et al., <i>Botulinum toxin type A: pharmacology</i> , in Mayer N., editor, <i>Spasticity: etiology, evaluation, management and the role of botulinum toxin</i> , 2002; pages 110-124, at 112-113
	CK	Bushara K., <i>Botulinum toxin and rhinorrhea</i> , Otolaryngol Head Neck Surg 1996;114(3):507
	CL	Cui, M., et al., <i>Mechanisms of the antinociceptive effect of subcutaneous BOTOX®: inhibition of peripheral and central nociceptive processing</i> , Naunyn Schmiedebergs Arch Pharmacol 2002; 365 (supp 2): R17
	CM	Dabrowski et al.; <i>Botulinum toxin as a novel treatment for self mutilation in Lesch-Nyhan syndrome</i> , Ann Neurol 2002 Sep;52(3 Supp 1):S157
	CN	Duggan et al.; <i>A surbey of Botulinum neurotoxin substrate expression in cells</i> ; <i>Mov Disord</i> , 10(3):376:1995
	CO	Fung L. K. et al., <i>Pharmacokinetics of Interstitial Delivery of Carmustine 4-Hydroperoxycyclophosphamide and Paclitaxel From a Biodegradable Polymer Implant in the Monkey Brain</i> , Cancer Research 58;672-684:1998
	CP	Gonelle-Gispert et al.; <i>snap-25a and -25b isoforms are both expressed in insulin-secreting cells and can function in insulin secretion</i> ; <i>Biochem J</i> 1;339 (pt 1):159-65:1999
	CQ	Guyton A.C. et al., <i>Textbook of Medical Physiology</i> , W.B. Saunders Company 1996, ninth edition; 686-688
	CR	Habermann E., et al., <i>Tetanus Toxin and Botulinum A and C Neurotoxins Inhibit Noradrenaline Release From Cultured Mouse Brain</i> , J Neurochem 51(2);522-527:1988
	CS	Habermann E., <i>Inhibition by Tetanus and Botulinum A Toxin of the release of [<sup>3</sup>H]Noradrenaline and [<sup>3</sup>H]GABA From Rat Brain Homogenate</i> , Experientia 44;224-226: 1988
	CT	Habermann, <i>I-Labeled Neurotoxin from Clostridium Botulinum A: Preparation, Binding to Synaptosomes and Ascent to the Spinal Cord</i> ; <i>Naunyn-Schmiedeberg's Arch. Pharmacol.</i> 1974; 281, 47-56

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	CU	<i>Harrison's Principles of Internal Medicine</i> (1998), edited by Anthony Fauci et al., 14 <sup>th</sup> edition, published by McGraw Hill
	CV	Heckmann M., et al., <i>Botulinum toxin type A injection in the treatment of lichen simplex: An open pilot study</i> , J Am Acad Dermatol 2002 Apr;46(4):617-9
	CW	Jacks, L., et al., <i>Idiopathic toe walking: Treatment with botulinum toxin A injection</i> , Dev Med Child Neurol 2002;44(Suppl 91):6, and foot dystonia (Rogers J., et al., <i>Injections of botulinum toxin A in foot dystonia</i> , Neurology 1993 Apr;43(4 Suppl 2
	CX	Jahanshahi M., et al., <i>Psychological functioning before and after treatment of torticollis with botulinum toxin</i> , J Neurol Neurosurg Psychiatry 1992; 55(3): 229-231
	CY	Jankovic J. et al., <i>Therapy With Botulinum Toxin</i> , Marcel Dekker, Inc., (1994), page 5, 150
	CZ	Jost W., <i>Ten years' experience with botulinum toxin in anal fissure</i> , Int J Colorectal Dis 2002 Sep;17(5):298-302
	CAA	Katsambas A., et al., <i>Cutaneous diseases of the foot: Unapproved treatments</i> , Clin Dermatol 2002 Nov-Dec;20(6):689-699
	CBB	Li Y, et al., <i>Sensory and motor denervation influences epidermal thickness in rat foot glabrous skin</i> , Exp Neurol 1997;147:452-462 (see page 459)
	CCC	Marjama-Lyons, J., et al., <i>Tremor-Predominant Parkinson's Disease</i> , Drugs & Aging 16(4);273-278:2000
	CDD	Moyer E et al., <i>Botulinum Toxin Type B: Experimental and Clinical Experience</i> , being chapter 6, pages 71-85 of "Therapy With Botulinum Toxin", edited by Jankovic, J. et al. (1994), Marcel Dekker, Inc.
	CEE	Murry T., et al., <i>Spasmodic dysphonia; emotional status and botulinum toxin treatment</i> , Arch Otolaryngol 1994 Mar; 120(3): 310-316
	CFF	Naumann et al; <i>Botulinum toxin type A in the treatment of focal, axillary and palmar hyperhidrosis and other hyperhidrotic conditions</i> ; <i>European J. Neurology</i> 6 (Supp 4): S111-S1150:1999
	CGG	Pearce, L.B., <i>Pharmacologic Characterization of Botulinum Toxin For Basic Science and Medicine</i> , Toxicon 35(9);1373-1412 at 1393
	CHH	Ragona et al.; <i>Management of Parotid Sialoceles With Botulinum Toxin</i> ; <i>The Laryngoscope</i> 109:1344-1346:1999
	CII	Sanchez-Prieto, J., et al., <i>Botulinum Toxin A Blocks Glutamate Exocytosis From Guinea Pig Cerebral Cortical Synaptosomes</i> , Eur J. Biochem 165;675-681:1997

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	CJJ	Schantz, E.J., et al, <i>Properties and use of Botulinum toxin and Other Microbial Neurotoxins in Medicine</i> , Microbiol Rev. 56;80-99:1992
	CKK	Sevim, S., et al., <i>Botulinum toxin-A therapy for palmar and plantar hyperhidrosis</i> , Acta Neurol Belg 2002 Dec;102(4):167-70
	CLL	Singh, <i>Critical Aspects of Bacterial Protein Toxins</i> , pages 63-84 (chapter 4) of Natural Toxins II, edited by B.R. Singh et al., Plenum Press, New York (1976
	CMM	Suputtitlada, A., <i>Local botulinum toxin type A injections in the treatment of spastic toes</i> , Am J Phys Med Rehabil 2002 Oct;81(10):770-5
	CNN	Weigand et al.; I-Labelled Botulinum A Neurotoxin: Pharmacokinetics in Cats after Intramuscular Injection; <i>Nauny-Schmiedeberg's Arch. Pharmacol.</i> 1976; 292, 161-165
	COO	Woolf C. et al., <i>Neuropathic Pain: Aetiology, Symptoms, Mechanisms, and Management</i> , Lancet 1999; 353: 1959-64

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